Reason: Failed to maintain a valid surety bond.

Bryant L. VanBrakle,

Director, Bureau of Tariffs, Certification and Licensing.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93E-0214]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lovenox®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Lovenox® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Lovenox® (enoxaparin sodium injection). Lovenox® is indicated for the prevention of deep vein thrombosis, which may lead to pulmonary embolism, following hip replacement surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lovenox® (U.S. Patent No. 4,692,435) from Choay S.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated July 15, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Lovenox® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Lovenox® is 1,777 days. Of this time, 1,322 days occurred during the testing phase of the regulatory review period, while 455 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* May 19, 1988. FDA has verified the applicant's claim that May 19, 1988, was the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 31, 1991. The applicant claims December 31, 1991, as the new drug application (NDA) effective date "to determine the applicable regulatory review period," but claims July 26, 1991, as the "initially submitted" date in its actual calculation of the length of the extension. FDA records indicate that the NDA for Levenox® (NDA 20-164) submitted on July 26, 1991, was incomplete. FDA refused to file this incomplete application and notified the applicant of this fact by letter dated September 20, 1991. The completed NDA was then submitted on December 31, 1991, which is properly considered to be the NDA's initially submitted date.

3. *The date the application was approved:* March 29, 1993. FDA has verified the applicant's claim that NDA 20-164 was approved on March 29, 1993.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 887 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 25, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 25, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93-28999 Filed 11-24-93; 8:45 am]

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